Table 1. Treatment schedule and outcome measures.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items | Before treatment | Administration period | At the end of the test | Post observation period |
| Time point |  | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 10 | Day 11 or at discharge before Day 10 | 1 week later （Day 17) | 1 year later（Day 365) |
| Tolerance | ― | ― | ― | ― | ― | ― | ― | ― |  | ― | (± 2 days） | (± 14 days） |
| Acquisition | 〇 |  |  |  |  |  |  |  |  |  |  |  |
| Confirmation of patient background | 〇 |  |  |  |  |  |  |  |  |  |  | 〇 |
| Administration of test drugs |  |  |  |  |  |  |  |  |  |  |  |  |
| Confirmation of subjective symptoms | 〇 |  |  |  |  |  |  |  |  | 〇 | 〇 | 〇 |
| Observation of adverse events |  |  |  |  |  |  |  |  |  | 〇 | 〇 | 〇 |
| Blood pressure | 〇 |  | 〇 | 〇 | 〇 | 〇 | 〇 | 〇 |  | 〇 |  |  |
| Estimation of body temperature and abdominal pain | 〇 | 〇 | 〇 | 〇 | 〇 | 〇 | 〇 | 〇 |  | 〇 |  |  |
| Weight | 〇 |  |  |  |  |  |  |  |  | 〇 |  |  |
| LAB data | Hematology examination | 〇 |  |  | 〇 |  | 〇 |  | 〇 |  | 〇 |  |  |
| Blood biochemical examination | 〇 |  |  | 〇 |  | 〇 |  | 〇 |  | 〇 |  |  |
| Urine examination | 〇 |  |  |  |  |  |  |  |  | 〇 |  |  |
| Confirmation of concomitant medication and supportive care | 〇 |  |  |  |  |  |  |  |  | 〇 |  |  |
| CT scan | 〇 |  |  |  |  |  |  |  |  |  |  |  |